DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2005

Ms. Stacy L. Lewis
Senior Regulatory Affairs Specialist
ALARIS Medical Systems, Incorporated
10221 Wateridge Circle
San Diego, California 92121-2733

Re: K043299
Trade/Device Name: Medley™ PCA Module with PCA/Monitoring Protocol
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEA
Dated: November 29,2004
Received: November 30,2004

Dear Ms. Lewis:

This letter corrects our substantially equivalent letter of December 10, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

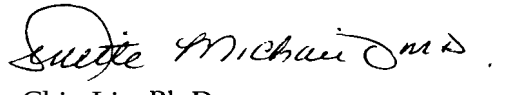
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, .including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K043299

Device Trade Name: **Medley™ PCA Module with PCA/Monitoring Protocol**

Indications For Use: The Medley PCA Module is intended for use in today's growing professional healthcare environment for facilities that utilize infusion devices for the delivery of medications or fluids. The Medley PCA Module is indicated for use on adults, pediatrics, and neonates for continuous or intermittent delivery through clinically acceptable routes of administration; such as intravenous (IV), subcutaneous, or epidural.

The addition of the PCA/Monitoring Protocol provides an optional and hospital-configurable feature that is intended to align with healthcare facilities' current protocols that require monitoring of patients while on PCA therapy. All device programming, data entry and validation of PCA/Monitoring Protocol parameters is performed by the trained healthcare professional according to hospital-defined protocol or a physician's order.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General, Restorative, and Infection Control, Dental Devices

510(k) Number: K043299

DEC 1 0 2004

SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems®
Medley™ PCA Module with PCA/Monitoring Protocol

SUBMITTER INFORMATION

A.	Company Name:	ALARIS Medical Systems, Inc.
B.	Company Address:	10221 Wateridge Circle San Diego, CA 92121-2733
C.	Company Phone: Company Fax:	(858) 458-7830 (858) 458-6114
D.	Contact Person:	Stacy L. Lewis Sr. Regulatory Affairs Specialist ALARIS Medical Systems, Inc.
E.	Date Summary Prepared:	November 29, 2004

DEVICE IDENTIFICATION

A.	Generic Device Name:	PCA Infusion Pump
B.	Trade/Proprietary Name:	Medley™ PCA Module
C.	Classification:	Class II
D.	Product Code:	MEA, PCA Infusion Pump

DEVICE DESCRIPTION

Due to the potential for opioid-induced respiratory depression, hospitals require regular monitoring and assessment of patients prescribed opioid medications. By allowing for the combination of a PCA Module and monitoring module (EtCO2 Module and/or SpO2 module) on the same platform, the Medley System provides a readily available way for the clinician to continuously monitor the patient's respiratory response while receiving opioid infusion therapy.

SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems®
Medley™ PCA Module with PCA/Monitoring Protocol

This submission will utilize the current system modularity to add a new hospital-configured Guardrails parameter (PCA/ Monitoring Protocol) to the Medley PCA Module. This Protocol is designed to help ensure patient safety when administering opioid medications. This Protocol will be available for use when a PCA Module and monitoring module(s) are attached to the same Medley Point of Care Unit (PCU). The PCA/Monitoring Protocol will be part of the Guardrails data set and will consist of a specified list of opioid medications and hospital-specified pre-configured monitoring limits. The Protocol will activate only when hospital-specified protocol indicates an unsafe state of respiratory depression is detected.

SUBSTANTIAL EQUIVALENCE

The ALARIS Medical Systems® Medley™ PCA Module with PCA/Monitoring Protocol is of comparable type and is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) No:	Date Cleared
Medley PCA Module	ALARIS Medical Systems, Inc.	K032233	Sept. 9, 2003

INTENDED USE

The Medley PCA Module with PCA/Monitoring Protocol is intended for use with patients that are prescribed PCA pain management therapy with opioid medications, specifically: Fentanyl, Demerol, Morphine, and Hydromorphone. The Medley PCA Module with PCA/Monitoring Protocol is intended for use by healthcare professionals in clinical environments. The Protocol does not replace clinician assessment or therapy decision making, but adds an additional safety net for the clinician at the point of care. All device programming, data entry and validation of the Medley PCA Module with PCA/Monitoring Protocol is performed by the trained healthcare professional according

SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems®
Medley™ PCA Module with PCA/Monitoring Protocol

INTENDED USE (continued)

to hospital-defined protocol or a physician's order. A separate Indications for Use page is located in **Section 6**.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Medley™ PCA Module with PCA/Monitoring Protocol and the predicate device has been performed. The results of this comparison demonstrate that the Medley™ PCA Module with PCA/Monitoring Protocol is equivalent to the marketed predicate device in technological characteristics.

PERFORMANCE DATA

The performance data indicate that the Medley™ PCA Module with PCA/Monitoring Protocol meets specified requirements, and is substantially equivalent to the predicate device.